CERTIFICATE OF ANALYSIS

(Certificate No. KMC022012-01)

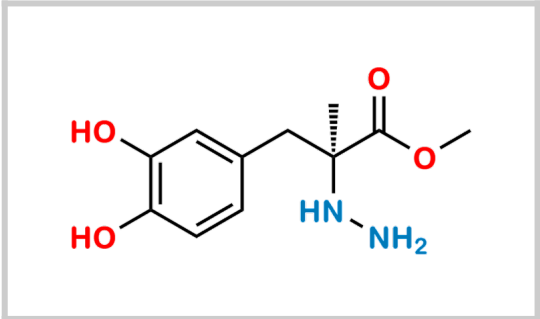
Release Date: 07/10/2024 **Re-test Date:** 06/10/2027

Carbidopa EP Impurity E

Identification

Chemical Name :
Methyl (2S)-3-(3,4-dihydroxyphenyl)-2-hydrazino-2-methylpropanoate (as per EP)

Alt. Name	: (S)-Carbidopa Methyl Ester ; Carbidopa Impurity 2
CAT No.	: KMC022012
CAS No.	: 52514-63-3
Molecular Formula	: C11H16N2O4
Molecular Weight	: 240.3



Analytical Information

Batch No.	: C022012-073-403	**Solubility**	: Methanol
Description	: Yellow Solid	**Mass**	: Confirm
HPLC Purity	: 93.99 %	**IR**	: Confirm
Weight Loss By TGA	: 0.73 %	**1H NMR**	: Confirm
% Potency	: 93.3 %		

Additional Information

Long Term Storage : Store at 2-8 deg. C for long term storage

Shipping Condition : Product is stable to be Shipped at Room Temperature

% Potency = [100 - 0.73(Weight Loss By TGA)] x [93.99(HPLC Purity)]/100 = 93.3 %

Recommendation : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		06/05/2025
Reviewed & Approved By	Quality Control	Jatin Patel		06/05/2025

Attachments : COA, HPLC, MASS, 1HNMR, IR and TGA